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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,989	12/13/2000	Johan H. Geerke	ARC2940R1	5705

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Paul B. Simboli
ALZA Corporation
1900 Charleston Road, Bldg. M10-3
P.O. Box 7210
Mountain View, CA 94039-7210

EXAMINER

DEWITTY, ROBERT M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,989

Applicant(s)

GEERKE, JOHAN H.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claims 1-26 are pending in the instant application. Claims 10-12 and 22-26 are withdrawn from further consideration as being drawn to a non-elected invention.

Election/Restrictions

1. Applicant's election with traverse of the restriction requirement in Paper No. 4 is acknowledged. The traversal is on the ground(s) that it would not be undue burden to search all originally filed claims, in particular those found in Groups II and III. This is not found persuasive because the inventions of II and III, as detailed in the Paper, are distinct from each other, and from the elected Group I. This is supported by their different classification, and divergent subject matter. Thus, examination of all claims would require searching in numerous classes, as well as expanding the search to cover different subject matter. This would clearly place undue burden on the examiner, and the resources of the patent office. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Applicant, in the preamble, has stated

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that the invention is "An improvement...". It is understood by the examiner that improvement refers to a matter of degree (for example, improving stability, improving therapeutic effect, etc.), however Applicant has provided no indication of the degree of improvement in the body of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-9, 13 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magruder et al. (U.S. Pat. No. 5,630,808).

Magruder teaches a delivery system for delivering a beneficial agent to an animal. The delivery system is manufactured as having a second wall section that aids in controlling fluid flux (col. 11, lines 1-4). The second wall may be formed from semipermeable materials (col. 11, lines 7-8). A beneficial agent formulation is contained within the delivery system in its interior (col. 10, lines 28-29). After assembly of the delivery system, a passageway is drilled into the end of the system (from the outside to the inside)(col. 18, lines 18-20). In example 21, it is taught that the passageway may be laser drilled through the wall for delivering the beneficial agent from the delivery system (col. 21, lines 18-20). The delivery system also contains a first

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wall section that surrounds the internal compartment that contains the beneficial agent (col. 10, lines 28-30). The first wall section can be made of glass, stainless steel and the like (col. 10, lines 57-58).

Whereas Magruder does not teach a barrier layer (a.k.a, first wall section) that remains intact during the formation of the exit orifice, as Magruder uses the same material as used in the instant invention in the first wall section (a.k.a., barrier layer), such a characteristic is inherent in the delivery system as taught by Magruder.

5. Claims 1-9 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magruder further in view of Theeuwes et al. (U.S. Pat. No. 4,088,864).

As stated above, Magruder refers to a delivery system comprised of a first wall, a second wall, a beneficial agent contained in the interior, and an exit passageway made by a laser. However, Magruder does not refer to a specific type of laser for making the passageway.

Theeuwes teaches making passageways in pills using lasers. It is taught that convention CO₂ lasers may be used, and lasers having higher or lower wavelengths will have an absorption of energy output (by the pill wall) this is less efficient. The use of such lasers (higher or lower wavelengths) will require greater power and/or firing duration (col. 4, lines 30-34).

Thus, based on the teachings of Theeuwes that CO₂ lasers are suitable for use in forming passageways, and Magruder teaching that laser can be used to form

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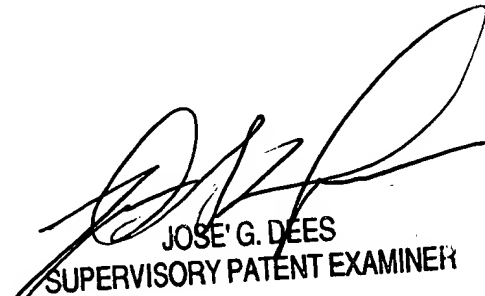
passageways, one with ordinary skill in the art would have been motivated to use CO₂ lasers to form the passageway in the delivery system of Magruder.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
March 11, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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